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DOCKET NO.: 10248.70023US00

#### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:

Adams et al.

Serial No.:

10/616,694

Confirmation No.:

1643

Filed:

July 9, 2003

For:

METHODS AND COMPOSITIONS RELATING TO ISOLEUCINE

BOROPROLINE COMPOUNDS

Examiner:

Not Yet Assigned

Art Unit:

1614

### CERTIFICATE OF MAILING UNDER 37 C.F.R. §1.8(a)

The undersigned hereby certifies that this document is being placed in the United States mail with first-class postage attached, addressed to MAIL STOP AMENDMENT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the day of April, 2005.

MAIL STOP AMENDMENT

Commissioner For Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

Transmitted herewith are the following documents:

- Information Disclosure Statement
- PTO Form 1449 with cited references
- Return Receipt Postcard

If the enclosed papers are considered incomplete, the Mail Room and/or the Application Branch is respectfully requested to contact the undersigned at (617) 646-8000, Boston, Massachusetts.

A check is not enclosed. If a fee is required, the Commissioner is hereby authorized to charge Deposit Account No. 23/2825. A duplicate of this sheet is enclosed.

Respectfully submitted, Adams et al., Applicant

By:

Maria A. Trevisan, Reg. No.: 48,207 Wolf, Greenfield & Sacks, P.C.

600 Atlantic Avenue

Boston, Massachusetts 02210-2206

Telephone: (617) 646-8000

Docket No.: I0248.70023US00

Date: April 28, 2005

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#### MAIL STOP AMENDMENT

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

# STATEMENT FILED PURSUANT TO THE DUTY OF DISCLOSURE UNDER 37 CFR §§1.56, 1.97 AND 1.98

Sir:

Pursuant to the duty of disclosure under 37 C.F.R. §§1.56, 1.97 and 1.98, the Applicant requests consideration of this Information Disclosure Statement.

#### PART I: Compliance with 37 C.F.R. §1.97

This Information Disclosure Statement has been filed before the mailing date of a first Office Action on the merits in the above-identified case.

No fee or certification is required.

Serial No.: 10/616,694 -2- Art Unit: 1614

Conf. No.: 1643

#### PART II: Information Cited

The Applicant hereby makes of record in the above-identified application the information listed on the attached form PTO-1449 (modified). The order of presentation of the references should not be construed as an indication of the importance of the references.

The Applicant hereby makes the following additional information of record in the above-identified application.

The above-identified U.S. application claims priority to application Serial No. PCT/US2003/021547. If the Examiner has not had the benefit of review of the file history of PCT/US2003/021547, then he/she is asked to contact the undersigned, who will provide a copy of same.

The Applicant would like to bring to the Examiner's attention the following co-pending applications that may contain subject matter related to this application:

Docket No.	Serial No.	Filing Date	Inventor(s)
10248.70012US00	09/578,363	25 May 2000	Wallner et al.
I0248.70013US00	09/290,376	12 April 1999	Wallner
I0248.70014US00	09/744,658	13 August 1999	Wallner
I0248.70022WO00	PCT/US2005/00079	10 January 2005	McLean et al.
*10248.70024US00	10/616, 409	9 July 2003	Adams et al.
*I0254.70007US01	11/030,591	6 January 2005	Bachovchin
*I0254.70008US01	10/775,598	10 February 2004	Bachovchin
*10254.70014US01	10/778,667	13 February 2004	Huber

<sup>\*</sup>a copy of this reference is not provided as the Office hereby waives the requirement under 37 CFR 1.98(a)(2)(iii) for submitting a copy of each cited U.S. patent application filed after June 30, 2003 and for applications filed before June 30, 2003, or that entered the national stage before June 30, 2003, if they are scanned to Image File Wrapper system and are available on Private PAIR.

#### PART III: Remarks

Documents cited anywhere in the Information Disclosure Statement are enclosed unless otherwise indicated. It is respectfully requested that:

1. The Examiner consider completely the cited information, along with any other information, in reaching a determination concerning the patentability of the present claims;

Serial No.: 10/616,694 - 3 - Art Unit: 1614

Conf. No.: 1643

2. The enclosed form PTO-1449 be signed by the Examiner to evidence that the cited information has been fully considered by the Patent and Trademark Office during the examination of this application;

3. The citations for the information be printed on any patent which issues from this application.

By submitting this Information Disclosure Statement, the Applicant makes no representation that a search has been performed, of the extent of any search performed, or that more relevant information does not exist.

By submitting this Information Disclosure Statement, the Applicant makes no representation that the information cited in the Statement is, or is considered to be, material to patentability as defined in 37 C.F.R. §1.56(b).

By submitting this Information Disclosure Statement, the Applicant makes no representation that the information cited in the Statement is, or is considered to be, in fact, prior art as defined by 35 U.S.C. §102.

Notwithstanding any statements by the Applicant, the Examiner is urged to form his own conclusion regarding the relevance of the cited information.

An early and favorable action is hereby requested.

Respectfully submitted, Adams et al., Applicant

Bv:

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600 Atlantic Avenue

Boston, Massachusetts 02210-2206

Telephone: (617) 646-8000

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Docket No.: I0248.70023US00

Date: April **28**, 2005

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FORM PTO-1449/A and B (Modified) MAY 0 2 7005 PPLICATION NO.: 10/616,694 ATTY. DOCKET NO.: I0248.70023US00 ILING DATE: July 9, 2003 CONFIRMATION NO.: 1643 INFORMATION DISCLOSURE STATEMENT BY APPLICATION APPLICANT: Adams et al. EXAMINER: Not Yet Assigned GROUP ART UNIT: 1614 of Sheet 1

#### U.S. PATENT DOCUMENTS

Examiner's	Cite	U.S. Patent Docum	nent	Name of Patentee or Applicant of Cited	Date of Publication or of issue	
Initials	No. Number Kind Code		Document	of Cited Document MM-DD-YYYY		
****	A1 4,499,082		Shenvi et al.	02-12-1985		
	A2	4,935,493		Bachovchin et al.	06-19-1990	
	A3	5,288,707		Metternich	02-22-1994	
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	A12	5,965,373		Zimmermann et al.	10-12-1999	
	A13	5,965,532		Bachovchin	10-12-1999	
*****	A14	6,040,145		Huber et al.	03-21-2000	
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	A18	6,300,314	B1	Wallner et al.	10-09-2001	
	A19	6,355,614	B1	Wallner	03-12-2002	
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•	A30	2005-0037976	A1	Wallner et al.	02-17-2005	

FOREIGN PATENT DOCUMENTS

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Initials	No.	Office/ Country	Number	Kind Code	Document (not necessary)	Cited Document MM-DD-YYYY	(Y/N)
	B1	EP	0 371 467	A2	Hoechst Aktiengesellschaft	06-06-1990	Y – Abst.
	B2	EP	0 615 978	A1	Adir et Compagnie	09-21-1994	Y – Abst.
	В3	EP	0 688 788	A1	Adir et Compagnie	06-22-1994	Y – Abst.
,,-	B4	wo	89/03223	A1	Bachovchin et al.	04-20-1989	

FORM PTO-1449/A and B (Modified)

# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

APPLICATION NO.: 10/616,694

ATTY. DOCKET NO.: I0248.70023US00

FILING DATE:

July 9, 2003

CONFIRMATION NO.: 1643

APPLICANT:

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Adams et al.

Sheet 2 of

GROUP ART UNIT: 1614

EXAMINER:

Not Yet Assigned

Examiner's	Cite	For	eign Patent Docum	ent	Name of Patentee or Applicant of Cited	Date of Publication of	Translation
Initials	No.	Office/ Country	Number	Kind Code	Document (not necessary)	Cited Document MM-DD-YYYY	(Y/N)
	B5	WO	91/16339	A1	New England Medical Center Hospitals, Inc.	10-31-1991	
	B6	wo	91/17767	Al	New England Medical Center Hospitals, Inc.	11-28-1991	
	B7	WO	92/12140	A1	Georgia Tech Research Corporation	07-23-1992	
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•	B12	WO	94/09132	Al	Dana-Farber Cancer Institute	04-28-1994	
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	B16	WO	98/50046	Al	Trustees of Tufts College	11-12-1998	
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	B19	WO	99/56753	Al	Point Therapeutics, Inc. 11-11-1999		
	B20	WO	99/62914	Al	Point Therapeutics, Inc. 12-09-1999		
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	B22	WO	00/71135	Αl	Point Therapeutics, Inc. 11-30-2000		
-	B23	WO	2004/004658	A2	Point Therapeutics, Inc.	01-15-2004	
	B24	WO	2004/004661	A2	Point Therapeutics, Inc.	01-15-2004	

## OTHER ART — NON PATENT LITERATURE DOCUMENTS

Examiner's Initials	Cite No	Include name of the author (in CAPITAL LETTERS) title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, relevant page(s), volume-issue number(s), publisher, city and/or country where published.	Transla (Y/N	
	C1	BAKER et al., Hydroxamates and aliphatic boronic acids: marker inhibitors for aminopeptidase. Biochemistry. 1983 Apr 26;22(9):2098-103.		
·	C2	BORLOO et al., Dipeptidyl peptidase IV: development, design, synthesis and biological evaluation of inhibitors. Verh K Acad Geneeskd Belg. 1994;56(1):57-88.		
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	C6	KELLY et al., The efficient synthesis and simple resolution of a proline boronate ester suitable for enzyme inhibition studies. Tetrahedron. 1993;49:1009-16.		
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FORM DTO	) 1440/A and B (M	odifia	4)	APPLICATION NO.:	10/616,694	ATTY. DOCKET NO.:	I0248.70023US00
FORM PTO-1449/A and B (Modified)  INFORMATION DISCLOSURE  STATEMENT BY APPLICANT				FILING DATE:	July 9, 2003	CONFIRMATION NO.	1643
				APPLICANT:	Adams et al.		
				GROUP ART UNIT:	1614	EXAMINER:	Not Yet Assigned
Sheet	3	of	4	GROOF ART ONIT.		EAAWIINEK.	Not let Assigned

Examiner's Initials	Cite No	Include name of the author (in CAPITAL LETTERS) title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, relevant page(s), volume-issue number(s), publisher, city and/or country where published.	Translation (Y/N)
	C8	KETTNER et al., Peptide boronic acid inhibitors of trypsin-like proteases, their preparation and use as anticoagulants and inflammation inhibitors. Chemical Abstracts. 1990;112:80. Abstract number 91790c.	
	C9	KINDER et al., Antimetastatic activity of boro-amino acid analog protease inhibitors against B16BL6 melanoma in vivo. Invasion Metastasis. 1992;12(5-6):309-19.	
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	C11	KINDER et al., Acylamino boronic acids and difluoroborane analogues of amino acids: potent inhibitors of chymotrypsin and elastase. J Med Chem. 1985 Dec;28(12):1917-25.	
•	C12	KUBOTA et al., Involvement of dipeptidyl peptidase IV in an in vivo immune response. Clin Exp Immunol. 1992 Aug;89(2):192-7.	
	C13	KUBOTA et al., Dipeptidyl peptidase IV (DP IV) activity in serum and on lymphocytes of MRL/Mp-lpr/lpr mice correlates with disease onset. Clin Exp Immunol. 1994 May;96(2):292-6.	
	C14	REINHOLD et al., Inhibitors of dipeptidyl peptidase IV (DP IV, CD26) induces secretion of transforming growth factor-beta 1 (TGF-beta 1) in stimulated mouse splenocytes and thymocytes. Immunol Lett. 1997 Jun;58(1):29-35.	
,	C15	SCANLAN et al., Molecular cloning of fibroblast activation protein alpha, a member of the serine protease family selectively expressed in stromal fibroblasts of epithelial cancers. Proc Natl Acad Sci U S A. 1994 Jun 7;91(12):5657-61.	
	C16	SCHARPE et al., Purified and cell-bound CD26: enzymatic inhibition, antibody binding profile, and expression on T cells in relation to other surface markers. Verh K Acad Geneeskd Belg. 1994;56(6):537-59.	
	C17	SCHON et al., Dipeptidyl peptidase IV in the immune system. Effects of specific enzyme inhibitors on activity of dipeptidyl peptidase IV and proliferation of human lymphocytes. Biol Chem Hoppe Seyler. 1991 May;372(5):305-11.	
	C18	SCHON et al., The dipeptidyl peptidase IV, a membrane enzyme involved in the proliferation of T lymphocytes. Biomed Biochim Acta. 1985;44(2):K9-15. Abstract Only.	
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	FORM PTO-1449/A and B (Modified)  INFORMATION DISCLOSURE		FILING DATE:	July 9, 2003	CONFIRMATION N	IO.: 1643	
_	EMENT BY			APPLICANT:	Adams et al.		
Chart		1 -6		GROUP ART UNIT:	1614	EXAMINER:	Not Yet Assigned
Sheet	1 4	l of	4				

Examiner's Initials	Cite No	Include name of the author (in CAPITAL LETTERS) title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, relevant page(s), volume-issue number(s), publisher, city and/or country where published.	Translation (Y/N)	n
	C27	WESLEY et al., A role for dipeptidyl peptidase IV in suppressing the malignant phenotype of melanocytic cells. J Exp Med. 1999 Aug 2;190(3):311-22.		
	C28	WOOD et al., Tetrapeptide inhibitors of the IgA1 proteinases from type I Neisseria gonorrhoeae. J Med Chem. 1989 Oct;32(10):2407-11.		
	C29	YOSHIMOTO et al., Comparison of inhibitory effects of prolinal-containing peptide derivatives on prolyl endopeptidases from bovine brain and Flavobacterium. J Biochem (Tokyo). 1985 Oct;98(4):975-9.		

EXAMINER:	DATE CONSIDERED:

#EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

[NOTE - The Office hereby waives the requirement under 37 CFR 1.98 (a)(2)(i) for submitting a copy of each cited U.S. patent and each U.S. patent application publication for all U.S. national patent applications filed after June 30, 2003 and for all international applications that have entered the national stage under 35 USC 371 after June 30, 2003. See 37 CFR 1.491(b). For all patent applications filed on or before June 30, 2003, copies of cited U.S. patents and patent application publications are still required unless an eIDS is filed. Copies of all other patent(s), publication(s), or other information listed must still be provided, even if it was previously submitted to, or cited by, the U.S. Patent Office in an earlier application, unless the earlier application is identified by the IDS and is relied upon for an earlier filing date under 35 U.S.C. §120, and the copy was provided in the earlier application.]

<sup>\*</sup>a copy of this reference is not provided as it was previously cited by or submitted to the office in a prior application, Serial No. \_\_\_, filed \_\_\_, and relied upon for an earlier filing date under 35 U.S.C. 120 (continuation, continuation-in-part, and divisional applications).